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|--|-------------|----------------------|------------------------------|------------------|
| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.          | CONFIRMATION NO. |
| 10/567,723   | 07/19/2006  | Kris De Roos         | GIV.P30089                   | 3958             |
| 23575 7590 02/06/2007<br>CURATOLO SIDOTI CO., LPA<br>24500 CENTER RIDGE ROAD, SUITE 280<br>CLEVELAND, OH 44145 |             |                      | EXAMINER<br>PUTTLITZ, KARL J |                  |
|  |             |                      | ART UNIT                     | PAPER NUMBER     |
|  |             |                      | 1621                         |                  |
| SHORTENED STATUTORY PERIOD OF RESPONSE   |             | MAIL DATE            | DELIVERY MODE                |                  |
| 3 MONTHS   |             | 02/06/2007           | PAPER                        |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/567,723

Applicant(s)

DE ROOS ET AL.

Examiner

Karl J. Puttlitz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/8/2006</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-4, 7 and 8 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the preparation of compounds of formula I by reacting cysteine and those specific sugars that conform to the sugar moiety of formula I does not reasonably provide enablement for the preparation of compounds of formula I by reacting cysteine with any sugar. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

"The standard for determining whether the specification meets the enablement requirement [in accordance with the statute] was cast in the Supreme Court decision of *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916) which postured the question: is the experimentation needed to practice the invention undue or unreasonable? That standard is still the one to be applied. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Accordingly, even though the statute does not use the term "undue experimentation," it has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). See also *United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217,

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1223 (Fed. Cir. 1988) ("The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation."). A patent need not teach, and preferably omits, what is well known in the art. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987); and *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984). Determining enablement is a question of law based on underlying factual findings. *In re Vaeck*, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991); *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984)." See M.P.E.P. § 2164.

In the instant case the claims cover a method for preparing compounds of formula I by reacting cysteine and any sugar, see claim 1. Based on the above standards, the disclosure must contained sufficient information to enable one skilled in the pertinent art to use this invention without undue experimentation. See M.P.E.P. 2164.01. Given the scope of the claims, it does not.

The state of the art does not confer any guidance regarding how those of ordinary skill would prepare compounds of formula I, which have a specific sugar moiety, by reacting cysteine with any sugar. Accordingly, the specification must make up for the deficiency in the state of the art.

However, the specification and the examples do not provide sufficient disclosure that would provide one of ordinary skill guidance to practice the invention, given the

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infinite amount of possible permutations of the sugars covered by the claims. In this regard, the disclosure does teach those of ordinary skill how to select appropriate co-catalyst, catalysts, and reaction mixtures, where the instant specification only describes specific sugars, see page 3, line 24+ , see M.P.E.P. § 2164.06(b) citing "*In re Vaeck*, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991), [where the court pointed to a] "limited disclosure by appellants of ... particular cyanobacterial genera operative in the claimed invention...." The claims at issue were not limited to any particular genus or species of cyanobacteria and the specification mentioned nine genera and the working examples employed one species of cyanobacteria."

The examiner understands that there is no requirement that the specification disclose every possible embodiment if there is sufficient guidance given by knowledge in the art (See M.P.E.P. § 2164.05(a) "[t]he specification need not disclose what is well-known to those skilled in the art and preferably omits that which is well-known to those skilled and already available to the public. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987); and *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984).").

However, the instant case goes beyond what is known in the art, because the specification does not offer any guidance on how one of ordinary skill would go about practicing the invention for every sugar.

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Applicant is reminded of the heightened enablement for chemical inventions. Specifically, the amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). The "amount of guidance or direction" refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly stated in the specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling. [I]n the field of chemistry generally, there may be times when the well-known unpredictability of chemical reactions will alone be enough to create a reasonable doubt as to the accuracy of a particular broad statement put forward as enabling support for a claim. This will especially be the case where the statement is, on its face, contrary to generally accepted scientific principles. Most often, additional factors, such as the teachings in pertinent references, will be available to substantiate any doubts that the asserted scope of objective enablement is in fact commensurate with the scope of protection sought and to support any demands based thereon for proof. [Footnote omitted.]

Here, the requirement for enablement is not met since the claims go far beyond the enabling disclosure.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The actual range of "n" in claim 1 is unclear.

Claims 3 states that the reaction is accelerated by heating. It is unclear if the claims actually requires heating, or it simply states an inherent property of the reaction. This portion of the rejection would be withdrawn if the claim were amended to positively recite "heating the reaction".

Claim 4 states that the reaction is carried out in the presence of a buffer having a pH from 1-9. It is unclear if the pH is referring top the reaction or the buffer.

Claim 6 provides for the use of a compound according to claim 1 but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 6 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35

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U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

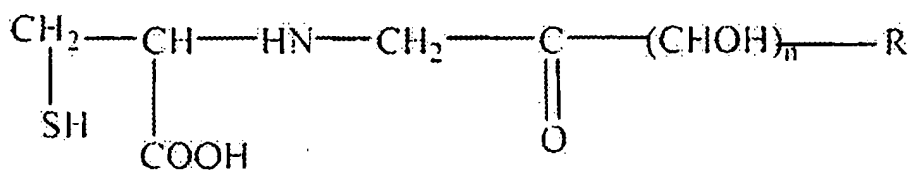
### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over each of applicant's admission, GB 1232719 (GB 719), GB 836694 (GB 694), GB 1082504 (GB 504) and U.S. Patent No. 4,592,917 to Tandy (Tandy).

The claims cover a compound of the formula I:



in which R is hydrogen when n=1-4, or methyl when n=0-3.

The claims also cover a method of preparing a compound according to claim 1, comprising the reaction of cysteine with a sugar in either aqueous solution or in a mixture of water and water-miscible solvents.

The claims also cover those embodiments wherein the reaction is accelerated by heating.



The claims also cover those embodiments wherein the reaction is carried out in the presence of a buffer having a pH of from 1-9.

The claims also cover a method of conferring a meaty flavour or aroma on a foodstuff, comprising the addition to the foodstuff before heating of a compound of the instant invention.

The claims also cover a use of a compound according to claim 1 to confer on a foodstuff a meaty flavour or aroma.

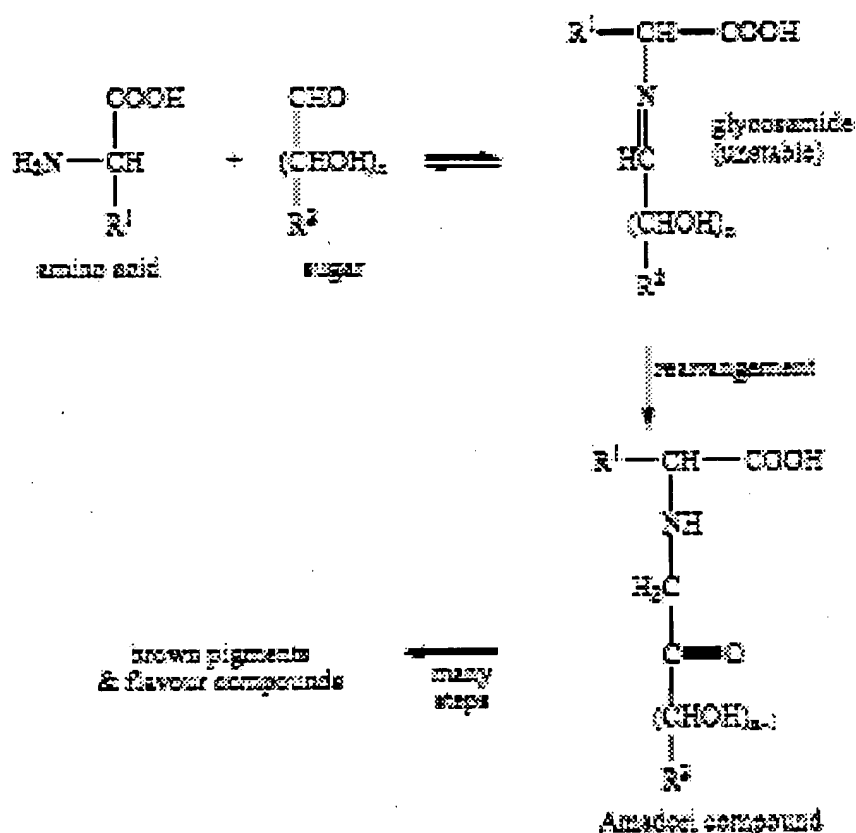
The claims also cover those embodiments wherein the reaction is accelerated by heating to a temperature between 60° and 100°C.

The claims also cover those embodiments wherein the buffer has a pH of from 2-6.

The claims also cover those embodiments wherein the compound is added in a concentration ranging from 5-5000 ppm by weight of foodstuff in consumable form.

The claims also cover those embodiments wherein the compound is added in a concentration ranging from 200-2000 ppm by weight of foodstuff in consumable form.

With regard to the above embodiments, Applicant admits that it is known that the formation of meat flavour proceeds via a sequence of steps known as the Maillard reaction. The sequence may be represented as follows:



Applicant also admits that one amino acid for which no Amadori compound has hitherto been identified is cysteine ( $\text{CH}_2(\text{SH})\text{CH}(\text{NH}_2)\text{COOH}$ ). Cysteine plays an important role in the development of flavour in meat, and this is believed to result from its ability to release hydrogen sulphide under the conditions of the Maillard reaction (see, for example, Kobayashi and Fujimaki in *Agric. Biol. Chem.*, 29, 698-81965). Numerous references have attributed to sulphur compounds a central role in the formation of meat flavours. However, unlike all other amino acids, cysteine has hitherto been believed to inhibit the Maillard reaction, because it tends to form relatively stable 2-glycosylthiazolidine-4-carboxylic acids, and this reaction competes with, and may

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even prevent, the formation of Amadori compounds. See pages 1 and 2 of the specification.

Alternatively, GB 719 teaches reactions of cysteine and sugars such as xylose, rabinose and xylose produce ingredients for meaty food flavoring, see page 1, lines 44+, and page 2 lines 37+ and 45+.

Alternatively, GB 694 teaches reactions of cysteine and sugars at the required pH's, see Example I.

Alternatively, GB 504 teaches reactions of cysteine and sugars at the required pH's, see Example I.

Tandy also teaches reactions of cysteine and sugars at the required pH's, see description bridging columns 2 and 3.

The difference between the compounds and process covered in the rejected claims and the compounds and process disclosed in the applied references is that the applied references do not explicitly teach the exact structure of formula I. However, given the reaction set forth in the specification at page 1 for preparing the claimed compounds is the same as described in the references, and given the fact that the specification teaches a reaction between cysteine and sugars (page 3, line 24+) which are the same as those used in the references, those of ordinary skill would expect that the claimed compounds are necessarily prepared by the applied references, and even more, the structure of these compounds are necessarily the same as that instantly claimed, see MPEP 2112.01 ("Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or

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substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977)."). Accordingly, the structure of the compounds of formula I are well within the motivation of those of ordinary skill, for the purpose of providing flavors, and therefore, *prima facie* obvious.

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karl J. Puttlitz whose telephone number is (571) 272-0645. The examiner can normally be reached on Monday to Friday from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at telephone number (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
**KARL PUTTLITZ**  
**PATENT EXAMINER**